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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,538	06/27/2003	Caius Rommens	058951-0167	5766

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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,538	<b>Applicant(s)</b> ROMMENS ET AL.	
	<b>Examiner</b> David T. Fox	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/23/06 & 8/30/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,5,13 and 44-57 is/are pending in the application.
- 4a) Of the above claim(s) 56 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,5,13 and 44-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 23 August 2006 have obviated the objections to the specification, the rejection under 35 USC 101, the outstanding indefiniteness rejection, and the art rejections for claims 3, 5, and 51-53. Applicant's Terminal Disclaimer of 23 August 2006 has obviated the obviousness-type double patenting rejection over copending application no. 10/505,079. The obviousness-type double patenting rejection over copending application no. 10/369,324 has been WITHDRAWN upon further consideration. It is now considered that the copending application's elected claims corresponded to Groups V-VI and VIII of the instant application, which were non-elected in response to a Restriction Requirement. The error is regretted.

Claims 3, 13, and 53 (newly amended) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly amended claim 3 replaces "selectable marker gene" with ---marker gene---. However, no basis in the specification has been pointed out for said change, and the Examiner can find none. Accordingly, claim 3 and dependents are directed to NEW MATTER. Applicant is invited to point out the basis in the specification for said amendment, or to amend claim 3 to restore the recitation of "selectable marker gene".

Claims 44-52 and 54-55 (newly amended) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44, 49, 51-52 and 54 all depend upon claim 3, and all recite "the selectable marker [gene]". However, newly amended claim 3 no longer recites "selectable marker gene". Accordingly, this phrase lacks antecedent basis in the above-mentioned claims. Dependent claims are included in the rejection.

Claims 3, 5, 13 and 44-55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 7-10 of the last Office action.

Applicant's arguments filed 23 August 2006 and 30 August 2006 have been fully considered but they are not persuasive. Applicant urges that there is adequate written description of the claimed genus of sequences, given the disclosure of a consensus sequence in the specification, the disclosure of methods for identifying plant-derived "border-like" sequences, and the later identification of 41 new "border-like" sequences comprising 25 bp and a particular consensus sequence as evidenced by Rommens et al (2005), appended to the Response of 23 August 2006.

The Examiner maintains that the claims are broadly drawn to a genus of "border-like" sequences of any sequence and from any plant, wherein said "border-like

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sequence" may be 5-100 bp long. See page 58 of the specification, paragraphs [0214] and [0215]. Said "border-like" sequences may include any sequence variant which has as low as 50% identity to any *Agrobacterium* T-DNA border sequence (see, e.g., page 58 of the specification, paragraph [0215]). No particular consensus sequence of any length is recited in the claims. Thus, the claims do not recite a genus of sequences which is commensurate in scope with what was exemplified. Furthermore, the claims do not recite the structure (consensus sequence) allegedly correlated with function (ability to transfer foreign DNA into the recipient plant genome) as required by *Lilly* cited previously.

Furthermore, the actual correlation between the consensus sequence and "border-like" function is unclear. Of the 41 putative "border-like" sequences taught by Rommens et al (2005), almost one-half failed to effect foreign DNA integration into tobacco genomes transformed therewith (see, e.g., page 1340, Figure 1).

Regarding the disclosure in the specification of an assay, see *Bayer v. Housey* below. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. Alternatively, disclosure of a method for producing a product does not reduce to practice the product itself. See *Bayer v. Housey*, 68 USPQ2d 1001, 1008-1009 (Fed. Cir. 2003): "processes of identification and generation of data are not steps in the manufacture of a final [drug] product".

Claims 3, 5, 13 and 44-55 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods of using 25 bp-long P-DNA borders from plants comprising the consensus sequence of SEQ ID

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NO:47 to transfer foreign DNA to the genome of heterologous plants, does not reasonably provide enablement for claims broadly drawn to any "border-like" sequence of any length or sequence, or its use to transfer foreign DNA to heterologous plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The scope of enablement rejection set forth on pages 10-13 of the last Office action has been withdrawn-in-part, in view of the evidence provided by the Rommens declaration under 37 CFR 1.132 filed 30 August 2006, and Rommens et al (2005) appended to the Response of 23 August 2006.

Applicant's arguments filed 23 August 2006 and 30 August 2006, as they pertain to the revised rejection above, have been fully considered but they are not persuasive.

Applicant urges that the scope of enablement rejection is improper, given the disclosure of a consensus sequence in the specification, the disclosure of methods for identifying plant-derived "border-like" sequences, the later identification of 41 new "border-like" sequences comprising 25 bp and a particular consensus sequence as evidenced by Rommens et al (2005), appended to the Response of 23 August 2006; and the ability of P-DNA "border-like" sequences from a variety of unrelated plant species to effect heterologous DNA transfer in tobacco transformed therewith, as stated in the Rommens declaration of 30 August 2006.

The Examiner maintains that the claims are not limited to the exemplified consensus sequence or length of border-like sequence which produced success, as

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stated above. Furthermore, Rommens et al (2005) support the Examiner's position regarding the unpredictability inherent in the process.

Rommens et al (2005) teach that modification of the genomic sequences flanking the putative "border-like" sequences greatly or completely reduces their DNA-transferring activity (see, e.g., page 1338, Abstract; page 1339). Rommens et al (2005) also teach that the mere presence of the consensus sequence is not predictive of DNA integrative function, and that sequence variation in said "border-like" sequences reduced or inhibited activity in over half of the cases (see, e.g., page 1339, column 2, top two paragraphs; page 1340, Figure 1).

Note also that Rommens et al (2005) teach that undesired retention of vector backbone sequences, i.e. non-plant sequences, was observed (see, e.g., page 1346, column 1, top paragraph). The instant specification teaches that the use of LifeSupport vectors with selectable marker genes may be employed to deter vector backbone integration, as stated in the last Office action, in the paragraph bridging pages 12 and 13. In contrast, the claims have been amended to delete the presence of a selectable marker gene. Thus, the claimed obtention of "native" plant transformants with no non-plant DNA is unpredictable, particularly in the absence of selectable marker genes as newly claimed.

Thus, given the claim breadth and unpredictability as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate and evaluate the DNA integration ability of a multitude of 5-100 bp long "border-like"

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sequences of any sequence, which possess as low as 50% identity to Agrobacterium T-DNA borders, in a multitude of unrelated plant species.

Claim 13 remains rejected under 35 U.S.C. 102(e) as being anticipated by McElroy et al (US 6,750,379 effectively filed 09 March 2000), as stated on pages 13-15 of the last Office action).

Applicant's arguments filed 23 August 2006 have been fully considered but they are not persuasive. Applicant urges that McElroy et al do not teach a method for using plant-derived "border-like" sequences for the integration of foreign DNA into the genome of transformed plant cells.

The Examiner acknowledges that the amended method claims are free of the prior art, as stated above. However, claim 13 is merely drawn to a transformed plant which comprises a plant-derived "desired polynucleotide" which comprises "at least a portion" of one "border-like" sequence. According to the specification, the "border-like" sequence may be as little as 5 bp long, and may possess as low as 50% identity with a T-DNA border from Agrobacterium. Furthermore, the specification does not set forth the size limits of such a "portion" of said "border-like" sequence. Accordingly, the claims read on any plant transformed with any plant-derived sequence, wherein said plants may comprise 1 base pair of a 5-25 base pair sequence of unspecified sequence. Such plants are taught by McElroy et al, who teach maize plants containing a maize HSP70 intron, wherein said maize plants would inherently contain at least one additional base pair, which base pair would be indistinguishable from the defined "portion" of a "border-like" sequence.



See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795.

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The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 13, 2006

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in black ink, appearing to read 'D. Fox', is written below the printed name and title.